

U.S.S.N. 08/359,937

Filed: December 20, 1994

Amendment

APPENDIX: Pending Claims Upon Entry of Amendment

13. (amended) [A] The method of claim 17 for delivering a drug to the nasal mucosa, comprising introducing a gas stream containing [a] the composition [according to Claim 1] into the nose.

14. (amended) [A] The method of claim 17 for treating diabetes comprising introducing a gas stream containing [a] the composition [according to Claim 1] into the nose, wherein the systemically active drug is insulin [into the nose].

17. (amended) A method for systemically delivering an active drug to a mammal, the method comprising:

- a) providing a composition comprising a plurality of bioadhesive microspheres comprising a material selected from the group consisting of polysaccharides, proteins, and synthetic polymers, wherein the polysaccharide is selected from the group consisting of a starch, a dextran, a hyaluronic acid, a gellan gum and pectin and the protein is selected from the group consisting of gelatin, albumin, and collagen, and an active drug selected from the group consisting of proteins and peptides, and non-protein drugs selected from the group consisting of antibiotics, anesthetics, vasoconstrictors, cardiotonics, vasodilators, antiseptics, bone metabolism controlling agents, hypotensives, sedatives, anti-tumour agents, anti-inflammatory agents, anti-histaminic agents, anti-allergic agents, and antitussive-expectorant agents, wherein at least 90 wt % of the microspheres in the composition have a diameter between 0.1 μm and 10 μm ; and
- b) administering the composition to a mammal intranasally thereby to systemically delivery a therapeutically effective amount of the drug to the mammal.

18. The method of claim 17 wherein the microspheres are prepared from a material that will gel in contact with the mucosal surface.

19. The method of claim 17 wherein the microspheres comprise a material selected from the group consisting of starch, gelatin, albumin, collagen and dextran.

20. The method of claim 19 wherein the microspheres comprise starch.

21. The method of claim 17 wherein the microsphere material is cross-linked prior to step b).

22. The method of claim 17 wherein the microspheres are heated to stabilize the microspheres prior to step b).

23. The method of claim 17 the composition provided in step a) further comprises an absorption enhancer.

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24. The method of claim 23 wherein the absorption enhancer is a surfactant.
25. The method of claim 17 wherein the drug is a biologically active peptide.
26. The method of claim 25 wherein the peptide is insulin or calcitonin.
27. The method of claim 17 wherein the microspheres comprise a material or ester thereof selected from the group consisting of polyvinyl alcohol, and polylactide-co-glycolide, hyaluronic acid, gellan gum and pectin.
28. The method of claim 17 wherein the microspheres comprise a material selected from the group consisting of hydroxyethyl starch, hydroxypropyl starch, carboxymethyl starch, cationic starch, acetylated starch, phosphorylated starch and grafted starch.